IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
ILLINOIS EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, ET AL., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	**Case No. 1:22-cv-00071**
	MDL 3026
	Hon. Rebecca R. Pallmeyer
This Document Relates to:	
ALL CASES	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Every plaintiff in this multidistrict litigation has alleged that cow's milk-based infant nutrition causes necrotizing enterocolitis ("NEC") in preterm infants. To prove that allegation, Plaintiffs need expert testimony. They have pointed to Dr. Logan Spector and Dr. Jennifer Sucre, who offered reports that purport to stand as proof of general causation in every case in this MDL. But for the reasons stated in Defendants' Rule 702 motions, the testimony of both experts should be excluded. Excluding these experts leaves Plaintiffs with no admissible expert testimony on the issue of general causation—requiring summary judgment in Defendants' favor in all cases. At a minimum, Defendants are entitled to summary judgment on all claims involving *fortifier*, a supplement to human milk, as Plaintiffs have not offered any general causation opinions as to those claims at all.

The law in all 50 States is clear: Plaintiffs ***must*** support complex scientific claims with admissible expert testimony. Plaintiffs here have failed to meet this burden for the reasons set forth in the accompanying motions to exclude their general causation experts. This failure is unsurprising, given the overwhelming scientific and medical consensus. Prompted by concerns that the claims in these lawsuits might severely harm preterm health, the scientific and medical community has spoken out against them. In a report commissioned by the Secretary of HHS, the National Institutes of Health Working Group ("NIH NEC Working Group") rejected the premise that preterm formula causes NEC and says that it is "the absence of human milk—***rather than the exposure to formula***"—that is associated with an increased risk of NEC. Decl. Ex. 2 (emphasis added). And a joint statement from three leading public health authorities recently declared that there is "no conclusive evidence that preterm infant formula causes NEC." Decl. Ex. 3. This consensus is why the American Academy of Pediatrics and the NEC Society—a charity dedicated to eradicating NEC—have advised that "[c]ourtrooms are not the best place to determine clinical

recommendations for the care of infants" and that this "litigation may result in unintended harmful consequences for babies" by threatening the availability of a "necessary" tool for neonatologists. Decl. Ex. 1 at 1; Decl. Ex. 13 at 1-2. In the absence of reliable, admissible expert testimony, Defendants are entitled to summary judgment in all pending cases.

At a minimum, Defendants are entitled to summary judgment on any claims based on the notion that cow's-milk-based ***fortifiers*** cause NEC, as Plaintiffs have no expert testimony supporting that theory at all. Indeed, one of Plaintiffs' experts concedes that there is simply not "an evidence base" on which to make a "determination" that fortifier is even ***associated*** with NEC. Decl. Ex. 4 at 282:25–283:11. There is certainly no evidence that it ***causes*** NEC.

FACTUAL AND PROCEDURAL BACKGROUND

I. NECROTIZING ENTEROCOLITIS

This litigation involves specialized preterm infant nutrition products selected by doctors in the neonatal intensive care unit ("NICU"). These products include formulas, which substitute for human milk when that milk is unavailable or medically inappropriate, and fortifiers, which are added to human milk to provide extra nutrients. Defs.' Statement of Undisputed Material Facts ("SUMF") ¶ 1. Due to their early birth and small size, preterm infants are at risk of developing NEC, a potentially devastating gastrointestinal disease. SUMF ¶¶ 2-4. Scientists have spent decades researching the causes of NEC and have concluded that the most prominent risk factor is prematurity. SUMF ¶ 6. Indeed, NEC almost exclusively develops in preterm infants, and ***all*** preterm infants are at risk of developing NEC—no matter what they are fed. SUMF ¶¶ 3-5. Other risk factors, also associated with prematurity, include hypoxia, very low birth weight, antibiotics, and anemia. SUMF ¶ 7.

Scientists agree that human milk—especially from the delivering mother—reduces the risk of NEC. SUMF ¶ 8. Because of protective elements naturally contained in human breastmilk,

which cannot be fully replicated in preterm formula, the scientific literature generally shows a dose-dependent relationship between the more human milk an infant receives and lower NEC rates. SUMF ¶ 9. But unfortunately, even preterm infants fed mother's milk develop NEC. SUMF ¶ 8. "These observations speak against the notion that components in infant formula trigger NEC and support the idea that bioactive components in human milk protect from NEC." SUMF ¶ 10.

A leading group of scientists recently reiterated this conclusion. On September 16, 2024, the NIH NEC Working Group issued a report concluding that the "[a]vailable evidence supports the hypothesis that ***it is the absence of human milk—rather than the exposure to formula***—that is associated with an increase in the risk of NEC." SUMF ¶ 12. (emphasis added). On October 3, 2024 FDA, CDC, and NIH issued a joint statement concluding that "[t]here is no conclusive evidence that preterm infant formula causes NEC," whereas "there is strong evidence that ***human milk is protective against NEC***." SUMF ¶ 13 (emphasis added).

II. PROCEDURAL BACKGROUND

The Judicial Panel on Multidistrict Litigation established this MDL in April 2022. *See* Decl. Ex. 7. Pursuant to the Court's Scheduling Order, on September 27, 2024, Plaintiffs disclosed seven experts, including experts on both general and specific causation. In reports expressly submitted in "ALL CASES," Decl. Exs. 8, 9, Plaintiffs' experts Dr. Spector and Dr. Sucre opined that cow's milk-based formula can cause NEC.[1] Dr. Spector, a non-physician epidemiologist undertaking his first career work on NEC, claims causation based on study data. Dr. Sucre, whose

[1] Plaintiffs disclosed in all cases Dr. Rebecca Betensky, a biostatistician who explicitly disclaimed that she was offering a causation opinion. *See* Decl. Ex. 10 at 129:10-12 (". . . you're not offering a causation opinion? A. I am not."). Similarly, Plaintiffs' case-specific experts expressly disclaimed having a general causation opinion. *See* Decl. Ex. 11 at 101:2-4 ("I'm not offering any opinions on general causation for this case."); Decl. Ex. 12 at 138:1-4 (". . . you're not going to provide an opinion in this case relating to general causation? A. Correct.").

research focuses on lung development, offers a mechanism of action opinion purporting to connect components in cow's milk-based formula with NEC—despite having never offered such an opinion in the peer reviewed literature—but otherwise defers to Dr. Spector with respect to her opinions on epidemiology, which she acknowledges are necessary to her causation opinion. Defendants have filed motions to exclude both. *See* Dkts. 592, 605.

LEGAL STANDARD

Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see, e.g.*, *Wackett v. City of Beaver Dam*, 642 F.3d 578, 581 (7th Cir. 2011). If, as here, "the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof," the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett,* 477 U.S. 317, 323 (1986) (citation omitted).

ARGUMENT

I. Expert Testimony Is Required on General Causation.

Causation is an essential element in every state law personal injury action.[2] *See, e.g.*, *In re Paraquat Prods. Liab. Litig.*, No. 3:21-MD-3004-NJR, 2024 WL 1655500, at *2 (S.D. Ill. Apr. 17, 2024) (all states "place the burden squarely on plaintiffs to produce evidence of a causal relationship" between product and their injury); *In re Mirena IUD Prods. Liab. Litig.*, 202 F. Supp. 3d 304, 310 (S.D.N.Y. 2016) (same), *aff'd*, 713 Fed. App'x 11 (2d Cir. 2017); *In re Bausch & Lomb Inc. Contacts Lens Sol. Prods. Liab. Litig.*, 693 F. Supp. 2d 515, 520 (D.S.C. 2010) (same),

[2] This includes the four states where the bellwether plaintiffs reside. *See, e.g.*, *Vicknair v. Pfizer, Inc.*, No. CV 20-2705, 2021 WL 2554935, at *2 (E.D. La. June 22, 2021); *Giddings v. Bristol-Myers Squibb Co.*, 192 F. Supp. 2d 421, 423 (D. Md. 2002); *Ward v. Ortho-McNeil Pharm.*, No. 5:14-CV-120-BO, 2015 WL 4110990, at *4 (E.D.N.C. July 7, 2015); *White v. Dow Chem. Co.*, 321 F. App'x 266, 273 (4th Cir. 2009).

aff'd sub nom. Fernandez–Pineiro v. Bausch & Lomb, Inc., 429 Fed. Appx. 249 (4th Cir. 2011).

Any plaintiff "must show both general and specific causation." *In re Bausch & Lomb*, 693 F. Supp. 2d at 518. General causation "examines whether the substance . . . had the capacity to cause the harm alleged," while specific causation "examines whether the substance did, in fact, cause the harm alleged." *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 831 (7th Cir. 2015) (internal citations omitted). Notably, Plaintiffs must prove general causation ***before*** turning to specific causation—"[w]ithout the predicate proof of general causation, the tort claim fails." *In re Zoloft (Sertralinehydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016), *aff'd sub nom. In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017) (citing *Wells v. SmithKline Beecham Corp.*, 601 F.3d at 375, 377–78 (5th Cir. 2010).

Plaintiffs in product liability cases involving complex medical issues—like these—must demonstrate causation through expert testimony. *See, e.g.*, *Mirena*, 202 F. Supp. 3d at 310 ("[T]he substantive law across all relevant jurisdictions holds that where a causal link is beyond the knowledge or expertise of a lay jury, expert testimony is required to establish causation") (internal quotations and citations omitted); *In re Paraquat Prods. Liab. Litig.*, 2024 WL 1655500, at *3 (same)*; see also Show v. Ford Motor Co*., 697 F. Supp. 2d 975, 983 (N.D. Ill. 2010) ("[P]roducts liability cases that involve complex products beyond a lay jury's understanding require expert testimony."), *aff'd*, 659 F.3d 584 (7th Cir. 2011). In such cases, expert testimony is necessary "because without it the jury is left to speculate on medical issues with which the average person is unfamiliar." *Mirena*, 202 F. Supp. 3d at 311; *see also Korte v. Exxonmobil Coal USA, Inc.*, 164 F. Appx. 553, 556 (7th Cir. 2006) ("Expert testimony is needed to establish causation in cases alleging an adverse health effect when the medical effects of exposure . . . are not within the ken of the ordinary person."). Indeed, the law of ***every*** jurisdiction, including the four bellwether

jurisdictions, requires Plaintiffs to offer expert testimony to satisfy this burden. *See* Appendix A (summarizing law); *see also In re: Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.* (No. II), 387 F. Supp. 3d 323, 341 (S.D.N.Y 2019), *aff'd*, 982 F.3d 113 (2d Cir. 2020) ("Other courts, surveying the law of the 50 states and territories, have concluded that each jurisdiction typically adheres to this principle.")

As a result, courts—including those overseeing MDLs with large numbers of cases—routinely grant summary judgment when plaintiffs fail to introduce admissible expert testimony on general causation. *In re Onglyza (Saxagliptin) & Kombiglyze XR (Saxagliptin & Metformin) Prods. Liab. Litig.*, No. 5:18-MD-2809-KKC, 2022 WL 3050665, at *10 (E.D. Ky. Aug. 2, 2022) ("Because the plaintiffs have not produced admissible expert testimony that saxagliptin is capable of causing heart failure, the defendants' motion for summary judgment must be granted."), *aff'd* 93 F.4th 339 (6th Cir. 2024); *In re: Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, No. 22MC3043, 2024 WL 3874183, at *1 (S.D.N.Y. Aug. 20, 2024); *In re Zoloft*, 176 F. Supp. 3d at 491; *Mirena No. II*, 387 F. Supp. 3d at 356.

II. Plaintiffs' Claims Require Expert Testimony on General Causation.

This litigation turns on medical causation issues that require expert testimony. Courts have found that, when "there is no obvious origin to an injury and it has multiple potential etiologies, expert testimony is necessary to establish causation." *Robinson v. Davol Inc.*, 913 F.3d 690, 695 (7th Cir. 2019) (internal citations and quotations omitted). The causation analysis is further complicated in cases where a "variety of exposures frequently can associate" with the alleged injury. *In re Onglyza*, 2022 WL 3050665, at *7. Such is the case here. Even Plaintiffs' experts concede that prematurity alone is a major risk factor for NEC and recognize numerous other risk factors to which premature infants are regularly exposed. SUMF ¶¶ 6-7.

All cases in this MDL allege injuries to preterm infants. Expert testimony is accordingly

necessary to establish that a factor ***other than prematurity***—like cow's milk-based formula—is also capable of causing NEC. *See In re Onglyza*, 2022 WL 3050665, at *8. These issues are patently "beyond the knowledge of expertise of a lay jury." *Mirena*, 202 F. Supp. 3d at 310.

As the contrary scientific consensus reflects, a lay person cannot determine causation based on differences in NEC rates between formula and human milk. *First*, assessing causation requires expertise in understanding this data and its limitations. *See, e.g.*, *In re Zoloft*, 176 F. Supp. 3d at 493 ("[W]hen epidemiological studies are equivocal or inconsistent with a causation opinion, experts asserting causation opinions must thoroughly analyze the strengths and weaknesses of the epidemiological research and explain why that body of research does not contradict or undermine their opinion."); *see also Harris v. CSX Transp., Inc.*, 753 S.E.2d 275, 282 (W. Va. 2013) ("An epidemiological association identified in a study may or may not be causal."). *Second*, it requires ruling out the universally recognized beneficial effects of human milk to instead identify specific harm from formula. *Third*, it requires determining if there is some specific component in formula that causes NEC. *See, e.g.*, Decl. Ex. 5 at 131: 22-25 (Dr. Sucre making this claim). Such theories are steeped in complex scientific principles and beyond the purview of a layperson.

Because Plaintiffs have not presented any scientifically reliable expert testimony as to general causation, they have failed to prove an essential element of each of their claims. As detailed in Defendants' Rule 702 motions, Dr. Spector relies on a faulty, made-for-litigation methodology that does not meet his own standards when conducting research for peers in the scientific community, and his analysis is limited to a population of infants distinct from any identified plaintiff in the MDL. *See* Defs.' Mot. to Exclude Dr. Spector (DE 605). Dr. Sucre offers a hypothesized mechanism of action based on animal and cellular models, but defers to Dr. Spector for her opinions regarding epidemiology, upon which her causation opinion fundamentally relies.

See Defs.' Mot. to Exclude Dr. Sucre (DE 592) at 5. Without the required expert testimony demonstrating that formula can cause NEC, Plaintiffs' claims fail as a matter of law.

III. At a Minimum, Summary Judgment Is Warranted on Claims Alleging That Fortifier Caused NEC.

In the alternative, even were the Court to find that Plaintiffs have proffered an admissible general causation opinion that *formula* can cause NEC, Defendants are still entitled to summary judgment on Plaintiffs' claims that cow's milk-based *fortifier* causes NEC. Many Plaintiffs in this litigation, including the infant in *Inman*, received both fortifier and formula, others only fortifier. *See, e.g.,* Decl. Ex. 14 at 34:23-25. None of Plaintiffs' general causation experts has offered the opinion that fortifier can cause NEC—indeed, they expressly disclaimed offering any such opinion. *See, e.g.*, Decl. Ex. 5 at 57:23-25 ("Again, I wasn't asked to render an opinion on fortifier.") (Sucre); Ex. 4 at 283:6-8 ("I am not offering an opinion on association between fortifier alone and—compared to human milk and causation of NEC.") (Spector). Dr. Spector explained that there is simply not "an evidence base to make [the] determination" that fortifier is associated with an increased risk of NEC—let alone that fortifier ***causes*** NEC. Decl. Ex. 4 at 282:25–283:11.

It is no surprise that Plaintiffs have failed to present general causation testimony on fortifier, given that no plaintiff in the larger NEC litigation—in any court—has attempted to present to a jury a claim that fortifier causes NEC. To the contrary, lawyers for other plaintiffs have argued that there is "absolutely no evidence that cow's milk-based fortifier increases NEC risk," Decl. Ex. 15 at 67:4-13, and "[w]e didn't think that was the legitimate claim that should be brought," Decl. Ex. 16 at 6160:10–14. These cases are no different and their fortifier claims are equally illegitimate. Without supporting expert testimony, they fail as a matter of law.

CONCLUSION

For the foregoing reasons, the Court should grant summary judgment on all claims.

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